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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/522,421	03/25/2005	Andreas Meyer	PC/4-32584A	8057
1095 7550 06/20/2008				
NOVARTIS CORPORATE INTELLECTUAL PROPERTY ONE HEALTH PLAZA 104/3 EAST HANOVER, NJ 07936-1080				
EXAMINER				
THOMAS, TIMOTHY P				
ART UNIT		PAPER NUMBER		
1614				
MAIL DATE		DELIVERY MODE		
06/20/2008		PAPER		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/522,421

**Applicant(s)**

MEYER ET AL.

**Examiner**

TIMOTHY P. THOMAS

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**Period for Reply** -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 13 March 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 17 and 27-32 is/are pending in the application.
- 4a) Of the above claim(s) 17 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 27-32 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/CDC)
- 4) ☐ Interview Summary (PTO-413)
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_
- Paper No(s)/Mail Date \_\_\_\_\_

**DETAILED ACTION**

***Response to Arguments***

1. Applicants' arguments, filed 3/13/2008, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.
2. Applicant's arguments, see p. 5, filed 3/13/2008, with respect to the rejections under 35 USC 102 and 103 have been fully considered and are persuasive. The rejections of the canceled claims have been withdrawn.
3. The previous prior art rejections are withdrawn for the following reasons:  
35 USC 102(e) anticipated by Tanizawa (US 2004/0018235 A1)

The new claims have been amended to require 10-20% pitavastatin and 20-50% microcrystalline cellulose in the inner phase of the composition and 15-40% matrix former (such as HPMC) in an outer phase. Tanizawa teaches less than 10% pitavastatin in the inner phase (12/256 in Ex 1; 4/91 in Ex 2; 8/133 in Ex. 13; etc.); only the Comparative Example 1 has 16/120 (13.3%), which does not contain two phases. The amended claims also require 14-40% matrix former at the outer phase, the values taught are smaller (all examples contain less than 10% in the outer phase). No microcrystalline cellulose is present in the inner phases.

35 USC 102(e) anticipated by Tillyer (US 2003/0211151 A1)

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Tillyer teaches HPMC as a sub-coating (which is further coated by polymers); even if considered "an outer phase", the HPMC amounts in the sub-coat would be 2.5-7.5%, significantly lower than 14-40%; no microcrystalline cellulose is present

35 USC 103 as obvious over Alberts

The HPMC in the coating of Examples 11-16 is less than 2% of the composition (the inner layer contains more HPMC); microcrystalline cellulose (Avicel PH101) is present in the inner phases at about 5%, significantly lower than the claimed range of 20-50%.

4. The following rejections are necessitated by the amendment presenting new claims.

***Claim Rejections - 35 USC § 112***

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 28-31 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Each of claims 28-31 depend on a canceled claim, which renders the subject matter of the claims indefinite.

7. Regarding claim 28, the phrase "such as" renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention.

See MPEP § 2173.05(d).

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8. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

9. Claims 27-32 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 32 contains new matter for the following reasons: The written basis in the specification closest to the new claim appears to be elected Example 4 (pp. 29-30).

Example 4 does not give written basis for the following reasons:

- a) Example 4 in the inner phase has two types of HPMC (3cps) and (100) cps at 5 wt % and 18.75 wt %, respectively, which are not required in claim 32;
- b) Example 4 cites, regarding pitavastatin, only the Ca-salt;
- c) Example 4 external phase contains (100'000 cps) HPMC, but the HPMC in claim 32 is not limited as to cps;
- d) Example 4 external phase requires 0.5 wt % of magnesium stearate, which is not in claim 32

For Claim 27, no single location in the specification was identified for the elements of the claim, references are scattered:

a) The amounts for pitavastatin appear on p. 14, 2nd paragraph "Drug Substance" and following line. The page 14 pitavastatin is given in percentage of the total composition but there is no total composition limitation in instant claims 27.

b) Microcrystalline cellulose appears on p. 14, 5-7th lines from bottom, which gives 20-52 %, in combination with preferred 50% in 6th line from bottom gives range claimed. The Inner phase discussed at the bottom half of page 14 of the specification is defined on page 14, lines 15-16, as a 4-, optionally 5-component phase, but in contrast, the claim 27 inner phase only requires 3 components.

c) Stabilizer range of 1-5, I cannot find...1-15 range is on p. 14, under "Stabilizer"; there are two 1-5 ranges in the 4th-5th lines of p. 14 for binder and disintegrants, but not applicable to stabilizer...I don't see a 5 anywhere.

### ***Conclusion***

10. No claim is allowed.

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

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extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to TIMOTHY P. THOMAS whose telephone number is (571)272-8994. The examiner can normally be reached on Monday-Thursday 6:30 a.m. - 5:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on (571) 272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Timothy P Thomas/  
Examiner, Art Unit 1614

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/Ardin Marschel/

Supervisory Patent Examiner, Art Unit 1614